Annexure-6

Scheme framed under regulation 9 of the Pharm.D Regulations, 2008 for -

- Pharm.D course
- Pharm.D. and Pharm.D. (Post Baccalaureate) course

Under this Scheme the application for consideration of approval u/s 12 of the Pharmacy Act, 1948 shall be submitted by an authority to the Pharmacy Council of India on Council's portal only.

1. <u>Eligibility Criteria</u>:

The following authorities shall be eligible to apply **online** in the prescribed format named SIF (Standard Inspection Form) as per following details -

Authorities

- a) The Central Government / State Government / Union Territory administration.
- b) An autonomous body established by the Central or State Government for the purpose of pharmacy education.
- c) A University.
- d) A society registered under the Societies Registration Act, 1860 (21 of 1860) or corresponding Acts in States.
- e) A public religious or charitable trust registered under the Trust Act, 1882 (2 of 1882) or the Wakfs Act, 1954 (29 of 1954).

2. **Qualifying Criteria**:

The following conditions shall be fulfilled by an applicant.

- a) The applicant shall not start, conduct or increase in intake in Pharm.D or Pharm.D. (Post Baccalaureate) course without the prior approval of the Pharmacy Council of India.
- b) Institutions running B.Pharm course approved under section 12 of the Pharmacy Act, 1948 for the purpose of registration as a pharmacist will only be permitted to run Pharm.D. course. The B.Pharm institutions approved for conduct of B.Pharm course are not eligible to start Pharm.D course.
- c) Pharm.D. (Post Baccalaureate) course will be permitted only in those institutions which are permitted to run Pharm.D. course.
- d) Number of admissions in the above said courses are restricted as below
 - i) Pharm.D. course 30 students.
 - ii) Pharm.D. (Post Baccalaureate) course 10 students.
- e) The applicant shall provide necessary infrastructure facilities including teaching staff as prescribed by PCI
 - i) under "Appendix-B" of Pharm.D. Regulations, 2008 for starting of the course.
 - ii) Minimum Qualification for Teachers in Pharmacy Institutions Regulations, 2014.

- f) <u>Location of the Hospital</u>
 - 1. Within the same limits of Corporation or Municipality or Campus with Medical Faculty involvement as adjunct faculty.
 - 2. If the institution and hospital are located in different Corporation or Municipality or Campus, the distance between the two shall not be more than 30 kms. by road.
- g) Only one Pharm.D institution can have the MOU with one hospital.

3. <u>Pre-requisite mandatory documents to be submitted</u>:

a) The institution shall submit the following documents for starting of new pharmacy institution / introduction of new Pharm.D course by existing institution –

For Private institutions / Government institutions

For Pharm.D course

- i) Consent of affiliation of Examining Authority.
- ii) MOU with 300 bedded hospital as per prescribed requirements under regulation 2) of Appendix-B of Pharm.D Regulations, 2008 except in North Eastern States and hilly regions of India where hospital with 300 beds strength are not available, the institutions desiring to seek approval of Pharm.D course are permitted to sign a Memorandum of Understanding with district headquarter hospital with available bed strength. The prescribed format of MOU is enclosed as Annexure-IV.

<u>For Central Government University / State Government University / Private</u> <u>University</u>

- i) If **new University**, a copy of Gazette Notification declaring it a University.
- ii) Relevant portion of Act / Gazette Notification empowering the University to start pharmacy programme, hold examination and confer diploma, degree.
- iii) In case University's statutes does not empower the University to start pharmacy course, then the University's resolution of Board of Governors / Board of Management / Syndicate / Governing Council / Authority of the University to start pharmacy programmes be submitted in the prescribed format. The prescribed format is enclosed as **Annexure-I.**
- iv) Certificate from Registrar of the University to the effect that University is willing to conduct the pharmacy examination in the prescribed format. The prescribed format is enclosed as **Annexure-II**.
- v) Dully filled in prescribed format for approval of the University as Examining Authority u/s 12(2) of the Pharmacy Act, 1948 in a prescribed format. The prescribed format is enclosed as **Annexure-III.**
- vi) MOU with 300 bedded hospital as per prescribed requirements under regulation 2) of Appendix-B of Pharm.D Regulations, 2008 except in North Eastern States and hilly regions of India where hospital with 300 beds strength are not available, the institutions desiring to seek approval of Pharm.D course are permitted to sign a Memorandum of Understanding with district headquarter hospital with available bed strength. The prescribed format of MOU is enclosed as **Annexure-IV**.

If New Deemed to be University

- i) The MHRD Notification declaring it as deemed to be University be issued.
- ii) Relevant portion of Act / Gazette Notification empowering the University to start pharmacy programme, hold examination and confer diploma, degree.
- iii) In case University's statutes does not empower the University to start pharmacy course, then the University's resolution of Board of Governors / Board of Management / Syndicate / Governing Council / Authority of the University to start pharmacy programmes be submitted in the prescribed format. The prescribed format is enclosed as **Annexure-I.**
- iv) Certificate from Registrar of the University to the effect that University is willing to conduct the pharmacy examination in the prescribed format. The prescribed format is enclosed as **Annexure-II.**
- v) Dully filled in prescribed format for approval of the University as Examining Authority u/s 12(2) of the Pharmacy Act, 1948 in a prescribed format. The prescribed format is enclosed as **Annexure-III.**
- vi) MOU with 300 bedded hospital as per prescribed requirements under regulation 2) of Appendix-B of Pharm.D Regulations, 2008 except in North Eastern States and hilly regions of India where hospital with 300 beds strength are not available, the institutions desiring to seek approval of Pharm.D course are permitted to sign a Memorandum of Understanding with district headquarter hospital with available bed strength. The prescribed format of MOU is enclosed as **Annexure-IV**.
- b) The submission of above document will be pre-requisite for access to application in SIF (Standard Inspection Form) and submission of Pharmacy Education Regulatory Charges.
- c) Online application in applicable prescribed form called SIF (Standard Inspection Form).
- d) The online application shall be submitted on PCI portal within the prescribed time period as announced by the PCI on its website www.pci.nic.in

4. <u>Pharmacy Education Regulatory Charges</u>

The details of online payment of Pharmacy Education Regulatory Charges $\$ are enclosed as Annexure - V

5. <u>Procedure</u>:

A. For New institutions

<u>Step-1</u> - Registration on the PCI portal.

- a) Type on web browser www.pci.nic.in
- b) Click on DIGI-PHARMed as available on right corner.
- c) New page will be open. Click on "Institute Registration" corner.
- d) A registration Form namely "user Management" will open.
- e) For first time registration, the institute needs to pay Rs.10,000/- as Pharmacy Education Regulatory Charges for registration to proceed further.

Step-2 - Payment of course-wise establishment fee which includes annual PERC.

- a) New institutions can apply for following courses only
 - i) D.Pharm
 - ii) B.Pharm
 - iii) M.Pharm (only Central Government / State Governments institutions)
- b) Institution shall pay course-wise establishment fee which includes annual PERC.
- c) Establishment fee is non-refundable.

<u>Step-3</u> - Submission of SIF and statutory documents.

- a) Institution shall submit the SIF along with the statutory documents as prescribed in the Schemes.
- b) If SIF and statutory documents are complete, window shall open for payment of course-wise security deposit.
- c) On receipt of security deposit, surprise inspection will be arranged u/s 16 of the Pharmacy Act, 1948 for verification of the facilities.
- d) A copy of the Inspection Report will be forwarded by the Pharmacy Council of India to the applicant for rectification of the deficiencies if any and submission of compliance report with documentary evidence.
- e) The Inspection Report will be placed in the Executive Committee / Central Council of the Pharmacy Council of India and the decision arrived at will be communicated to the applicant.
- f) The decision of the Central Council shall be final.
- g) If SIF and statutory documents are in-complete

If SIF and statutory documents are in-complete, application will be rejected. The establishment fee will not be refunded being non-refundable.

B. For existing institutions applying for new course

(applicable from 2023-2024 academic session, applications for 2022-2023 academic session are already received)

Step-1

- a) Requirements with regard to submission of statutory documents as prescribed in Para 3 of the Scheme will be verified and deficiencies if any will be communicated by the PCI within 7 days after the submission of the documents.
- b) The institution shall submit the compliance within 7 days of the communication of the PCI and if found compliant the institution will be permitted to progress towards the SIF submission and payment of as Pharmacy Education Regulatory Charges for registration within the last date of the submission of the applications.
- c) In the event of compliance not being received within the 7 days or not found correct, the application will be processed for consideration of extension of existing courses only.

Step-2

- a) In case application is complete / compliance of statutory documents is submitted, institution will apply in SIF and submit the prescribed as Pharmacy Education Regulatory Charges for registration. The said SIF will be processed for considering approval process.
- b) The physical inspection will be conducted by the Pharmacy Council of India u/s 16 of the Pharmacy Act, 1948 for verification of the facilities.
- c) A copy of the Inspection Report will be forwarded by the Pharmacy Council of India to the applicant for rectification of the deficiencies if any and submission of compliance report with documentary evidence.
- d) The Inspection Report will be placed in the Executive Committee / Central Council of the Pharmacy Council of India and the decision arrived at will be communicated to the applicant.
- e) The decision of the Central Council shall be final.

6. Syllabus:

The syllabus for each subject of study shall be as prescribed by the PCI from time to time as per regulation 8 of "The Pharm.D Regulations, 2008".

<u>On Letter head of the University</u> (to be enclosed with SIF)

<u>Resolution of Board of Governors / Board of Management / Syndicate /</u> <u>Governing Council / Authority of the University</u>

- 1. A meeting of Board of Governors / Board of Management / Syndicate / Governing Council / Authority of the University was held on _____.
- 2. It was decided to establish the following pharmacy courses in the institution -

Tick (\checkmark) relevant course in pharmacy

D.Pharm	()
B.Pharm	()
* M.Pharm	()
** Pharm.D/Pharm.D(PB)	()
** B.Pharm (Practice)	()

- * M.Pharm course cannot be started till B.Pharm course is approved u/s 12 of the Pharmacy Act, 1948 for the purpose of registration as a pharmacist. The B.Pharm institutions approved for conduct of B.Pharm course are not eligible to start M.Pharm course. However, the institutions established by the Central Government/State Govt. for the purpose of imparting postgraduate education shall be eligible for starting M.Pharm course directly.
- **Pharm.D / Pharm.D (PB) / B.Pharm (Practice) course (s) cannot be started till B.Pharm course is approved u/s 12 of the Pharmacy Act, 1948 for the purpose of registration as a pharmacist. The B.Pharm institutions approved for conduct of B.Pharm course are not eligible to start Pharm.D / Pharm.D (PB) / B.Pharm (Practice) course (s).
- 3. A copy of the resolution of Board of Governors / Board of Management is enclosed as Annexure- A

Name of Registrar.....

Signature

Date.....

On Letter head of the University (to be enclosed with SIF)

It is hereby certified that examinations for the following pharmacy courses will be held as per the statutory provisions of the Pharmacy Act, 1948 and the Regulations framed there under -

Tick (\checkmark) relevant course in pharmacy

D.Pharm	()
B.Pharm	()
* M.Pharm	()
** Pharm.D/Pharm.D(PB)	()
** B.Pharm (Practice)	()

- * M.Pharm course cannot be started till B.Pharm course is approved u/s 12 of the Pharmacy Act, 1948 for the purpose of registration as a pharmacist. The B.Pharm institutions approved for conduct of B.Pharm course are not eligible to start M.Pharm course. However, the institutions established by the Central Government/State Govt. for the purpose of imparting postgraduate education shall be eligible for starting M.Pharm course directly.
- **Pharm.D / Pharm.D (PB) / B.Pharm (Practice) course (s) cannot be started till B.Pharm course is approved u/s 12 of the Pharmacy Act, 1948 for the purpose of registration as a pharmacist. The B.Pharm institutions approved for conduct of B.Pharm course are not eligible to start Pharm.D / Pharm.D (PB) / B.Pharm (Practice) course (s).

Name and Sigr	nature of Registrar /	Secretary of Board of Examining Authori (applicable for stand alone D.Pharm institution)	
Name :			
Signature :			
Date :			

Format for approval of the Examining Authority u/s 12(2) of the Pharmacy Act

(As approved by 73rd Central Council (Sept., 2004) under Item No.143)

Details of Examining Authority

A)	Name of the Examining Authority with complete Postal Address	
	with complete 1 ustal Address	
		STD Code
		Telephone
		Fax No
		E-Mail
B)	Name, Designation and Address of Vice Chancellor/Registrar	
	Chancehoi/Registrai	
		STD Code
		Telephone
		Office
		Residence
		Fax No
		E-Mail

- C) Whether the Examining Authority is
 - Statutory Indian University
 - Body constituted by the Central or State Government

Yes/No Central Govt./State Govt. D) Name of the Pharmacy institutions affiliated to Examining Authority.

For D.Pharm course

(If the number is more, please enclose the details as Appendix-I)

For B.Pharm course

(If the number is more, please enclose the details as Appendix-II)

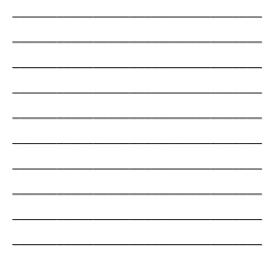
For M.Pharm course

(If the number is more, please enclose the details as Appendix-III)

For Pharm.D and Pharm.D (PB) course

(If the number is more, please enclose the details as Appendix-IV)

For B.Pharm (Practice) course



(If the number is more, please enclose the details as Appendix-V)

E) Details of Examining Committee of Examining Authority -

S.No.	Name of Chairman (Pharmacy qualified		Details of En	nployment		Signature
	persons) and Expert Member (Pharmacy qualified persons) of Examining Committee	Name of Instt. where presently employed	Designation	Qualification	Experience	
	<u>Chairman:</u>					
	<u>Expert Member :</u>					

F) Norms for appointment of Examiners for Pharmacy Examination (Both Theory & Practicals) be enclosed.

G) <u>DETAILS OF EXAMINATION CENTRES APPROVED BY THE EXAMINING</u> <u>AUTHORITY.</u>

- i) Please enclose List of Examination Centres approved by the Examining Authority for conduct of D.Pharm examination (Appendix-VI).
- ii) Please enclose List of Examination Centres approved by the Examining Authority for conduct of B.Pharm examination (Appendix-VII).
- iii) Whether following facilities are provided in the Examining Centres
 - a) adequate rooms with necessary furniture for holding written examinations. please enclose details as **Appendix-VIII**
 - b) Well equipped laboratories for holding practical exams. please enclose details as **Appendix-IX**

H. <u>UNDERTAKING BY THE EXAMINING AUTHORITY TO FOLLOWING EFFECT</u> :

- It shall permit the Inspector or Inspectors of the Pharmacy Council of India to visit and inspect the examinations.
- It shall, if so required by a candidate, furnish the statement of marks secured by a candidate in the examinations after payment of prescribed fee, if any, to the Examining Authority.
- In pursuance of sub-section (3) of section 12 of the Pharmacy Act, 1948, the Examining Authority shall communicate to the Secretary, Pharmacy Council of India not less than six weeks in advance the dates fixed for examinations, the time-table for such examinations, so as to enable the Council to arrange for inspection of the examinations.

Name of the Registrar_____ (In Capital Letters)

Signature______ with date

SS/Examining(b)/hd-6/p.1-4/28.7/30.7.2004 Am;vk/28.7/cl/29.7.04

Annexure-IV

MEMORANDUM OF UNDERSTANDING (To be executed on Rs.100/- Non-judicial stamp paper) (applicable for Pharm.D course)

This memorandum of understanding is made on _____Day____month ____Year

between

_____Hospital [with full address/affiliating bodies] which is represented by its

Principal/Dean / Medical Superintendent/Medical Director/CEO herein named as party one

and

_____College of Pharmacy (with full address and affiliating bodies) represented by

its Principal/Director/Dean herein named as party two

The parties hitherto agree as follows:

- Party one declares that ______ (name of the hospital) is a ______ (number) bedded hospital, with a minimum of 120 beds for General Medicine Department.
- Party one agrees to provide to party two the minimum space necessary of 1200 square feet in the hospital building to establish Pharmacy Practice department for the conduct of Pharm.D programs.
- **3.** Party one agrees to provide preceptors required to train the Pharm.D students.
- **4.** Party one agrees that, it will not enter into similar agreement with any other Pharmacy institution/s or department/s offering or intend to offer Pharm.D programs.
- 5. Party one declares that -
 - a) Hospital and institution with which it is signing the MOU are within the same limits of Corporation or Municipality or Campus with Medical Faculty involvement as adjunct faculty.
 - OR
 - b) If the institution and hospital are located in different Corporation or Municipality or Campus, the distance between the two is not more than 30 kms. by road.

Tick the relevant





Signature

Signature

- **6.** The prospective students will be allowed to undergo training in the following specialty departments
 - Medicine
 - Surgery
 - Pediatrics
 - Gynecology and Obstetrics
 - Psychiatry
 - Skin and VD
 - Orthopedics
- Party two will provide the academic staff and necessary infrastructure for Pharm. D course as per the PCI norms and takes the overall responsibility for smooth conduct of the programs.
- 8. This agreement is to be in effect at least for ten years from the time of its endorsement by both the parties. The Hospital will not sign the MOU for sharing of the hospital facilities with any other Pharm D institution till the present agreement / MOU is in effect.
- **9.** The officials representing _____hospital and _____college are signing this MOU to achieve the beneficial objectives of Pharm.D programs.

Signature Hospital authority [party one] with seal and date Signature Principal, [party two] College of Pharmacy with seal and date

Approved Pharmacy Education Regulatory Charges (PERC) for Pharmacy Courses for New and Existing Institutions

- 1. For new Institutions –PERC are applicable from 2022-23 academic session. New institutions are required to pay only the PERC for establishment of the new institutions which includes fee for registration, technical scrutiny and contingent changes besides 2 inspections. This also includes the annual PERC.
- 2. For existing Institutions –PERC are applicable from 2023-24 academic session
- 3. The existing institutions are also required to deposit the security deposit as per following details
 - a) For institutions running B.Pharm, Pharm.D / Pharm.D (PB) courses in 3 equal parts within 3 years.
 - b) For institutions running D.Pharm, M.Pharm and B.Pharm (Practice) courses in 2 equal parts within 2 years.

	Pharmacy Education Regulatory Charges (PERC) in Rupees, GST on PERC (on all categories) as per applicable rate has to be paid except for Security Deposit												
S No.	Category of PERC	D.Pha		B.Pha		M.Pl		Pharm.D/Pha		B.Pharm (Practice)		
		State / Central Government	Private	State / Central Government	Private	State / Central Government	Private	State / Central Government	Private	State / Central Government	Private		
1.	Establishment of new institutions/ Course This fee is for registration, technical scrutiny and contingent changes and for 2 inspection including annual PERC (Non- Refundable)	50,000	3,00,000	3,00,000	6,00,000	1,00,000 per specialization	2,00,000 per specialization	4,00,000	8,00,000	50,000	3,00,000		
2.	Security Deposit (refundable after 10 years)	-	50,00,000	-	50,00,000 (upto 60 seats) 1 Crore (upto 100 seats)	-	15,00,000 per specialization	-	2 Crore	-	25,00,000		

Pharmacy Education Regulatory Charges (PERC) in Rupees, GST on PERC (on all categories) as per applicable rate has to be paid except for Security Deposit													
S No.	Category of PERC	D.Pha	arm	B.Pha	arm	M.P	harm	Pharm.D/Pharm.D (PB)		B.Pharm (Practice)			
110.	TERC	State / Central Government	Private	State / Central Government	Private	State / Central Government	Private	State / Central Government	Private	State / Central Government	Private		
3.	Annual PERC	1,00,000	2,00,000	2,00,000	4,00,000	1,00,000 per specialization	2,00,000 per specialization	3,00,000	6,00,000	1,00,000	2,00,000		
4.	For increase in intake	50000	1,00,000	2,00,000	4,00,000	1,00,000 per specialization	200000 per specialization	Not Applicable	Not Applicable	50,000	1,00,000		
5.	For verification of compliance	100000	1,00,000	1,00,000	1,00,000	1,00,000	1,00,000	1,00,000	1,00,000	1,00,000	1,00,000		
6.	Maximum intake	60	60	100	100	15 per specialization	15 per specialization	Pharm.D- 30 Pharm.D (PB)- 10	Pharm.D- 30 Pharm.D (PB)- 10	40	40		
7.	Change in Name of Institutions	50,000	50,000	50,000	50,000	50,000	50,000	50,000	50,000	50,000	50,000		
8.	Change in Name of Trust	50,000	50,000	50,000	50,000	50,000	50,000	50,000	50,000	50,000	50,000		

	Pharmacy Education Regulatory Charges (PERC) in Rupees, GST on PERC (on all categories) as per applicable rate has to be paid except for Security Deposit													
S No.	Category of PERC	D.Pha	arm	B.Pha	arm	M.P.	harm	Pharm.D/Pha	arm.D (PB)	B.Pharm (Practice)			
INO.	IERC	State / Central Government	Private	State / Central Government	Private	State / Central Government	Private	State / Central Government	Private	State / Central Government	Private			
9.	Change in Examining Authority	50,000	50,000	50,000	50,000	50,000	50,000	50,000	50,000	50,000	50,000			
10.	Change of Hospital	Not Applicable	Not Applicable	Not Applicable	Not Applicable	50,000 (Applicable to only for M.Pharm (Practice)	50,000 (Applicable to only for M.Pharm (Practice)	50,000	50,000	Not Applicable	Not Applicable			
11.	Closure of Course	50,000	50,000	50,000	50,000	50,000	50,000	50,000	50,000	50,000	50,000			
12.	Closure of Institutions	1,00,000	1,00,000	1,00,000	1,00,000	1,00,000	1,00,000	1,00,000	1,00,000	1,00,000	1,00,000			

NOTE:

Security Deposit

- 1. The security deposit will be for a period of 10 years or till the closure of course/institute, whichever is earlier. At the end of 5th year 50% of interest earned will be given to institute and 50% interest will be transferred to PCI fund. At the end of 10th year: 50% of the further interest earned with the principal amount of security deposit will be given to institute and 50% of the interest earned will be transferred to PCI fund.
- 2. Security deposit will have to be deposited by the new institution only if the SIF including pre-requisite mandatory statutory documents (NOC of the State Government, consent of affiliation of the Examining Authority as applicable) are complete.